K091881

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Summit Harmar, LLC
2075 47th Street
Sarasota, Florida 34234
Phone: (941) 351-2776
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JUL - 1 2009

Contact Person: Kevin Kaminski
Director, Global Sourcing and Logistics

Date Prepared: June 22, 2009

Name of Device

RPL/CPL Vertical Platform Lift

Common or Usual Name

Wheelchair Elevator

Classification Name

Wheelchair Elevator

Predicate Device

Bruno VPL 3100 Vertical Platform Lift **(K061514)**

Intended Use

The VPL Series Vertical Platform Lift is intended to transport persons with a mobility disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

Device Description

The Harmar Summit, LLC Models RPL and CPL Vertical Platform Lifts are AC powered, patient transport devices designed for use in both residential and commercial applications. Their intended function and use is to transport persons with a mobility

disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

The RPL lift is designed for residential applications and will support a maximum load of 600 lbs. The CPL lift is designed for commercial or public applications, and will support a maximum load of 750 lbs.

Substantial Equivalence

The Summit Harmar RPL/CPL Vertical Platform Lifts are substantially equivalent to the Bruno VPL 3100 Vertical Platform Lift **(K061514).**

Performance Data

The Residential Platform Lift (RPL) is designed to conform with the following standards;

- ASME A18.1, Section 2 – Vertical Platform Lifts
- CSA B44.1 / ASME 17.5 – Elevator and Escalator Electrical Equipment
- ASME A18.1, Section 5 – Private Residence Vertical Platform Lifts

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Harmar Summit, LLC
% Mr. Kevin Kaminski
2075 47th Street
Sarasota, Florida 34234

Re: K091881
Trade/Device Name: Harmar Summit RPL/CPL Vertical Platform Lifts
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: June 24, 2009
Received: June 24, 2009

Dear Mr. Kaminski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Harmar Summit RPL/CPL Vertical Platform Lifts

Indications for Use:

The intended use of the Harmar Summit RPL/CPL Vertical Platform Lifts is to transport persons with a mobility disability, either in a wheelchair or ambulatory, up and down between levels of a residential or public facility.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091881